REMARKS/ARGUMENTS

The foregoing amendments have been made in response to the official action of September 19, 2007. Claims 1 and 50 have been amended to clarify that the combination of the arteriotomy staple and the pledget relates to an individual staple and pledget in which:

- the staple has sufficient stiffness to pierce tissue solely in response to a distal force applied at the proximal end and without supplemental support of the prongs,
- the proximal end of the staple is configured to enable closure of the staple prongs solely by manipulation of the proximal end of the staple, and
- the pledget is retained on the staple by the engagement of the edges of the pledget with the prongs.

These limitations are present in claim 1 as well as in each of the remaining claims by reason of their direct or indirect dependency from claim 1.

THE CITED PRIOR ART

U.S. Patent 5,972,004 (Williamson)

Williamson discloses a wire fastener of generally U-shaped form as seen in FIG. 1A below.

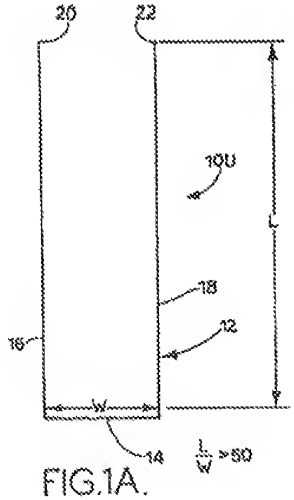


FIG.1A.

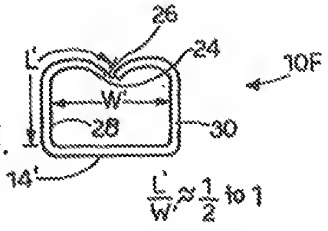


FIG.1B.

The legs 16, 18 of the fastener are suture-like, having pointed distal ends 20, 22 and are joined, at their other ends, to a crown member 14. The length L of the legs is "many times" the width of the crown and are long enough to extend out of the patient when the crown is disposed at the suture site. (6:42-46, 62-66). The length-to-width ratio of the fastener can be as much as 100 or more. (8:2-4). The device is placed with the use of a series of tools including an initial tool 40 shown in FIG. 2 below and is later cut and crimped to the shape of FIB. 1B above, with another, separate tool.

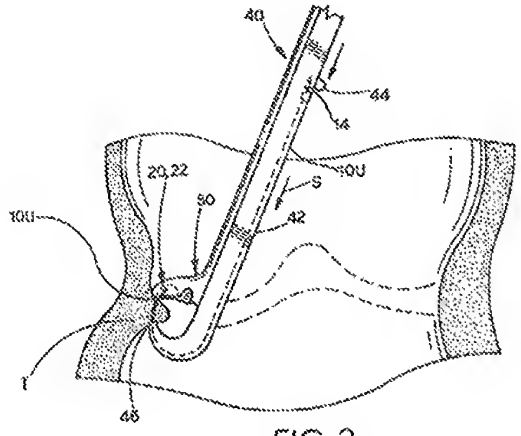


FIG. 2.

The initial tool 40 includes a track (described but not shown in the drawing) in which the fastener is placed with the crown 14 located proximally and the sharp tips 20, 22 located distally. (13:53-55). A trigger 74 is operated to move the fastener and force its pointed ends 20, 22 through the tissue. Then a handle 80 is operated to cause a grabber 50 to grip the pointed tips to draw them and the legs 16, 18 proximally through the tissue until the crown is pulled against the tissue. Another tool 60 (FIG. 22) is used to cut the legs 16, 18 to form the staple and bend the free ends 24, 26 of the staple to the configuration of FIG. 1B.

Williamson explains that a pledget 40 can be placed on the fastener so that it is interposed between the crown of the fastener and the tissue. (12:53-56). There is no other discussion of interaction between the pledget and the fastener or the configuration of the pledget.

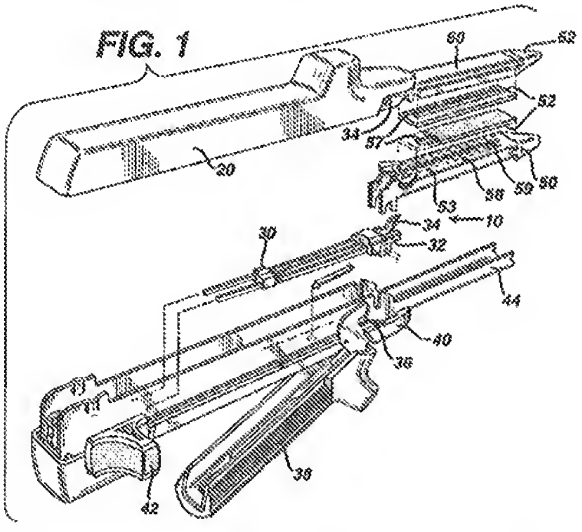
U.S. Patent 5,634,931 (Kugel)

Kugel discloses a hernia mesh patch configured to enable a sutureless repair. It is adapted to be folded and inserted through a relatively small incision in the region of the hernia.

Its structure facilitates manually positioning to cover the herniated region and certain of its surfaces are configured to help maintain the patch in place without fasteners. The patch may be of the order of about eight centimeters wide and about ten centimeters long. (8:48-50). The position retaining elements include holes 59 (7:66-8:1). Other embodiments include projections 82, scalloped or fringed circumferential edges 88 to frictionally hold the hernia mesh patch in place. (8:37-44). Although the Kugel hernia patch is adapted to make "sutureless repair", for large hernia mesh patches may be kept from sliding by using a limited number of anchoring stitches placed without creating tension or contributing to the strength of the repair. (4:60-67; 9:8-14). There is no disclosure in Kugel of any fastener of any staples or the like.

U.S. Patent 6,273,897 (Dalessandro)

The Dalessandro '897 patent describes a linear cutter stapling device by which a plurality of laterally spaced rows of staples are applied on opposite sides of a tissue cut. (1:11-17). The arrangement is illustrated in FIG. 1, reproduced below.



The stapler includes a pair of jaws 20, 40, one (40) of which is adapted to carry a staple cartridge 50 with at least two laterally spaced rows of staples (3:27-28). The other jaw 20 includes an anvil 60 with staple closing depressions in alignment with the rows of staples in the cartridge. (1:20-25). An elongate buttress 52 extends over the surface of the staple cartridge and another buttress 52 extends over the surface of the anvil 60. A knife 34 is advanceable longitudinally of the jaws to cut the tissue and the buttresses 52 after they have been stapled. The buttresses

(pledgets) 52 are secured to the stapler. (1:46-47). Dalessandro '897 describes pledgets that are "...releasably attachable to the staple cartridge and/or the anvil of a surgical stapling apparatus without conventional pins, clips, welds or adhesive." (1:56-59). To that end, the buttresses 52 are provided with longitudinally extending projections 57 that extend into longitudinal channels formed respectively in the cartridge and in the anvil to hold the buttresses 52 in a "releasable pressure fit" (3:40; 4:59-62).

After the tissue segments have been clamped between the buttresses by the jaws, the stapler is fired to drive the staples in the parallel lines of staples through the openings 53 in the cartridge. The staples pierce the buttresses and the tissue and the distal ends of the staples are formed to a B-shape or flat shape by engagement with the anvil. The knife 34 is advanced distally to cut the gripped tissue sections and buttresses between the parallel lines of staples. (7:22-45).

U.S. Patent 6,277,140 (Ginn)

Ginn discloses a vascular closure clip in the form of a resilient spring clip having an expanded (stressed) delivery configuration and an unstressed deployed configuration, as illustrated in FIGS. 3A-3D below:

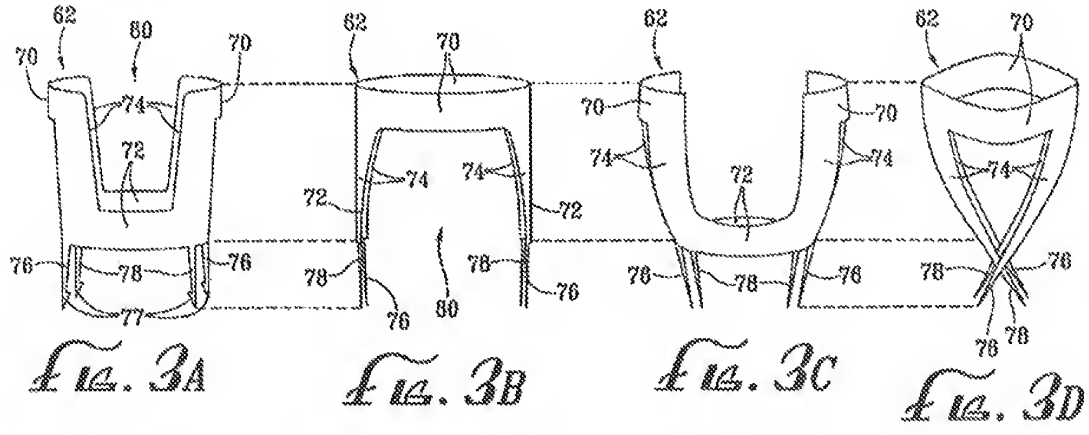


FIG. 3A FIG. 3B FIG. 3C FIG. 3D

The clip is advanced to the puncture site in the vessel while in the stressed configuration of FIGS. 3A and 3B. When the deployment device releases the stress, the clip returns to its relaxed, unstressed state of FIG. 3D, drawing tissues together.

CLAIM REJECTIONS – 35 U.S.C. §102

Reconsideration is requested of the rejection of claim 1 as anticipated by Williamson '004. Williamson does not disclose or relate to a device for closing an arteriotomy. Additionally, Williamson fails to disclose a combination pledget and staple in which the tissue piercing distal tips 20, 22 have sufficient stiffness to pierce tissue solely in response to a distal force applied at the proximal end (14 in Williamson) and without supplemental support of the prongs. The very long legs 16, 18 in Williamson are suture-like and appear to require containment within tracks associated with the delivery device 40. In contrast, with applicants' claimed invention, no supplemental support of the prongs is required and they can be driven into tissue solely in response to a distally directed force applied at the proximal end of the staple. Williamson requires that the sharp distal tips 20, 22 be gripped at the distal end of the legs 16, 18 and then that they be separately gripped by another instrument and then pulled by the distal tips 20, 22 until the crown end is fully seated.

Additionally, Williamson fails to disclose a combined staple and pledget in which the proximal end of the staple is configured to enable the delivery device to control closure of the staple prongs solely by manipulation of the proximal end of the staple.

Finally, Williamson does not disclose the claimed arrangement in which the pledget has edges configured to be frictionally engaged by and between the prongs to capture and retain the pledget on the staple solely by the engagement of the pledget and prongs. While Williamson discloses the use of a pledget, it is silent as to any particular inter-engagement between the fastener and the pledget. There is no disclosure of the claimed frictional engagement of edges of a pledget with prongs of the type called for by the claim.

Claim 50 depends from claim 1 and is not anticipated by Williamson for the same reasons.

CLAIM REJECTIONS - 35 §103

The §103(a) Rejections Are Improper Because They Do Not Resolve and Articulate the Level of Skill That Was Applied

The rejections under 35 U.S.C. §103(a) are improper because they fail to resolve and articulate the level of ordinary skill in the art that was applied. One of the essential underlying

factual elements that must be determined under the Supreme Court decisions of *Graham v. John Deere Co.*, 383 U.S. 1 (1966) and *KSR International v. Teleflex, Inc.*, 127 S. Ct. 1727, 82 USPQ2d 1385 (2007) is that the level of skill must be resolved. The action fails to indicate what level of skill was applied in the §103(a) rejections. That failure leaves insufficient basis to test the correctness of the rejection. The failure to articulate the level of skill is, itself, a basis for withdrawal of the rejection.

Claims 3, 4 and 48

Reconsideration is requested of the rejection of claims 3, 4 and 48 as unpatentable under 35 U.S.C. §103(a) in view of the combined disclosures of Williamson '044 and Kugel '931. Each of claims 3, 4 and 48 depends directly from claim 1, as amended, and includes all of the limitations discussed above in connection with claim 1. Even if Kugel were properly combinable with Williamson (which applicants would dispute), Kugel fails to disclose those features of applicants' invention that are missing from Williamson. Kugel does not disclose a pledget capable of use in connection with an arteriotomy, as required by the claims. Kugel discloses a relatively large hernia mesh patch having dimensions of the order of about 8 to 10 centimeters. There is nothing in Kugel to suggest any association with staples of any kind. To the contrary, Kugel relates to a hernia patch intended to be "sutureless". Kugel also fails to disclose or suggest an arrangement in which a pledget and an arteriotomy staple having the characteristics set forth in claim 1 may be joined by frictionally engaging edges of the pledget by and between the prongs. Where neither Williamson nor Kugel disclose these features of applicants' invention, their combination cannot be considered to do so. Certainly the rejection offers no reason for combining Kugel and Williamson in any manner, much less in the manner of applicants' claimed invention. Where Williamson and Kugel are directed to completely unrelated subjects, there is no showing of any reason or motivation for making the combination other than to select elements, piecemeal from the prior art, in order to try to meet applicants' claims. That is improper hindsight reasoning.

To the extent that the rejection is based on the notion that Kugel "teaches a pledget" that is incorrect, or that Kugel teaches "tab 62 configured to be received between said plurality of prongs," that, too, is incorrect. There is nothing in Kugel referring to staples or prongs or the function of the tabs as having anything to do with staple prongs. The holes 59 also have nothing

to do with prongs of a surgical arteriotomy staple. The holes are to facilitate the positioning of the hernia mesh patch, not for receiving prongs of an individual staple having the characteristics called for by the claim. Indeed, given the dimensions of the patch, it would seem impossible to place an arteriotomy staple, which would be of few millimeters in dimension, with its prongs extending through the large, widely spaced holes 59.

Claims 5-17

Reconsideration is requested of the rejection of claims 5-17 as unpatentable over the combined disclosures of Williamson '004 and Dalessandro '897. Williamson fails to disclose a number of features of applicants' claimed invention discussed above in connection with claim 1. Dalessandro fails to disclose those features of applicants' claimed invention that are missing from Williamson. Dalessandro does not disclose an arrangement in which the staple is configured to enable closure of the prongs solely by manipulation of the proximal end of the staple or a pledget that is retained on the staple by engagement of the edges of the pledget with the prongs. In Dalessandro the pledgets are attached to the surface of the cartridge and the anvil. Where these features are missing from each of Williamson and Dalessandro, there is no basis to conclude that the combination of those references could result in applicants' claimed invention.

Claim 49

Reconsideration is requested of the rejection of claim 49 as unpatentable under 35 U.S.C. §103(a) over the combined disclosures of Williamson and Ginn '140. Ginn does not disclose a pledget or the claimed interaction between the edges of a pledget and the staple prongs of the individual arteriotomy staple, nor does it include a FIG. 28 referred to in the rejection.

The claims are considered to be allowable.

Respectfully submitted,

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